AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

1. (currently amended): A method of performing interactive clinical trials for testing a new drug for cancer related studies, the method comprising:

a) performing a pre-clinical phase in which a computer model for ~~pharmacokinetics~~ pharmacodynamics of a drug is determined based on data obtained from *in vitro* studies of the effect of the drug in animal cells, and optionally, *in vivo* studies in animals, and ~~pharmacodynamics~~ pharmacokinetics of the drug is determined based on data obtained from ~~created and adjusted based on in vitro studies and~~ *in vivo* ~~in vivo~~ studies in animals;

b) performing a phase I clinical trial in which a clinical trial on at least a single dose of the drug of (a) is administered to at least one human, and the phase I clinical trial is performed in parallel with performing computer simulations of the computer model~~, wherein the phase I clinical trial comprises a plurality of sub-steps~~;

c) adjusting the computer model based on comparison of the results of the clinical trial ~~to the~~and computer simulations of the computer model wherein the at least a single dose of step (b) is incrementally increased in at least one dose escalation steps;

d) ~~determination~~calculation of the dose escalation step by the computer simulations of the computer model in step (c) to obtain ~~of~~ a maximal tolerated dose, minimum effective dose, and a recommended dose ~~based on the phase I clinical trial, in conjunction with the computer simulations~~;

e) checking the drug for cumulative effects after administration and providing this information to the computer model;

f) performing multiple simulations using the computer model with different doses and dosing intervals for different indications and patient populations;

g) determining, based on step f simulations results, an optimal regimen for the most responsive patient populations and clinical indications for a phase II clinical trial;

h) performing at least one phase II clinical trial where a number of small scale clinical trials are performed in parallel in order to test the optimal treatment regimen from step g for different pairs of clinical indications and patient populations;

~~i) analyzing interim results of step h, to choose the most promising regimens for continued clinical trials;~~

ji) performing at least one phase III clinical trial for step g chosen clinical indications by step i chosen regimens; and

kj) performing at least one phase IV clinical trial for post-marketing subpopulation analysis and long term product safety assessment.

2. (currently amended): The method of claim 1, wherein in step b, computer simulations of the model are performed prior to ~~each sub-step of~~ the phase I clinical trial, to predict results of the ~~sub-step~~phase I clinical trial, and the predicted results are compared to the phase I ~~sub-step~~ clinical trial results and the computer model is adjusted based on the comparison.

3. (previously presented): The method of claim 1, wherein a first decision whether to continue the phase II clinical trial is made prior to step h, stopping the trial if an adverse decision is made.

4. (previously presented): The method of claim 1, wherein results of step g are used to define clinical indications and define sub-groups of patients most sensitive, susceptible and responsive to the drug.

5. (previously presented): The method of claim 4, wherein effective treatment regimen is defined for a subset of the subgroups.

6. (previously presented): The method of claim 1, wherein the computer model is adjusted based on whether the clinical trial indicates a result higher than a threshold in at least one of pre-clinical, phase I and phase II trials.

7. (previously presented): The method of claim 1, wherein in step h, the small clinical trials are performed in parallel for a chosen clinical indication by a chosen treatment regimen.

8. (previously presented): The method of claim 3, wherein in step i, the most promising trials are chosen for clinical indications most sensitive to the drug administered via the most efficient regimen.

9. (previously presented): The method of claim 8, wherein in step i, a second decision whether to continue the phase III clinical trial is made, stopping the trial if an adverse decision is made.

10. (withdrawn): The method of claim 9, wherein the second decision is based on a prediction of safety profile of the new drug in the most promising trial compared with safety of pre-existing therapies.

11. (previously presented): The method of claim 9, wherein the decision is based on a prediction of efficacy profile of the new drug in the most promising trial compared with efficacy of pre-existing therapies.

12. (withdrawn): The method of claim 1, wherein step j is performed to prove safety of the drug.

13. (original): The method of claim 1, wherein step j is performed to prove efficacy of the drug.

14. (previously presented): The method of claim 1, when hitherto unknown effects are discovered in step j, the computer model is adjusted to obtain predictions for new regimens, patient populations and clinical indications.

15. (currently amended): A method of performing interactive clinical trials for a new drug for cancer related studies, the method comprising a step of performing a pre-clinical phase in which a computer model for pharmacokinetics and pharmacodynamics is created and adjusted based on data obtained from in vitro studies and optionally *in vivo*~~in vivo~~ studies in animals, wherein the computer model is an in silico patient that interacts with the results of the pre-clinical trials.

16. (currently amended): A method of performing interactive clinical trial for a new drug for cancer related studies, the method comprising a step of performing a phase I clinical trial wherein a dose-escalation is performed in parallel with computer simulations of the computer model to predict results and the prediction is compared with clinical results and the comparison is used to adjust the computer model, wherein the computer model is an in silico patient that interacts with the clinical trials.

17. (currently amended): A method of performing interactive clinical trials for a new drug for cancer related studies, the method comprising: developing a strategy for a ~~next sub-step~~

~~in~~ phase I clinical trial wherein the phase I clinical trial is performed in ~~conjunction~~ parallel with simulated computer predictions, and

wherein the simulated computer predictions comprises using a computer model that is an in silico patient that interacts with the clinical trials.

18. (new): A method of performing interactive clinical trials for a new drug for cancer related studies the method comprising a step of performing a phase II clinical trial wherein at least one clinical trial is performed in parallel with computer simulations of a computer model,

wherein the prediction is compared with clinical results from the phase II clinical trials and the comparison is used to adjust the computer model, wherein the computer model is an in silico patient that interacts with the clinical trials.

19. (new): A method of performing interactive clinical trials for a new drug for cancer related studies; the method comprising a step of performing a phase III clinical trial in parallel with computer simulations of a computer model that predicts a better treatment for the design of further clinical trials,

wherein the prediction is compared with clinical results from the phase III clinical trials and the comparison is used to adjust the computer model, wherein the computer model is an in silico patient that interacts with the clinical trials.

20. (new): A method of performing interactive clinical trials for a new drug for cancer related studies the method comprising a step of performing a phase IV clinical trial in parallel with computer simulations of a computer model that predicts post-marketing efficacy of a drug, and long term drug safety assessment,

wherein the prediction is compared with clinical results from the phase IV clinical trials and the comparison is used to adjust the computer model, wherein the computer model is an in silico patient that interacts with the clinical trials.